FEB 2 2 2001 K010025

Delasco
608 13th Avenue
Council Bluffs, IA 51501 USA

Dermatologic Lab & Supply, Inc
Delasco Information Systems

1-800-831-6273 including P.R. & Canada Local & International: 1-712-323-3269 24-Hour Fax: 1-712-323-1156

510(k) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME:	Delasco Electricator
COMMON NAME:	Electrosurgical Generator
CLASSIFICATION NAME:	Electrosurgical Cutting and Coagulation Devices and
Accessories,	878.4400.

The Delasco Electricator is a non-sterile, reusable, electrosurgical generator, designed to generate high frequencies (RF) of high voltage and low amperage current.

The Electricator is intended to be used for the removal and destruction of skin lesions and the coagulation of tissue. The Electricator Handpiece is an integral component used in conjunction with the generator.

The Delasco Electricator is substantially equivalent to the ConMed Hyfrecator 2000, manufactured by Aspen Labs and is substantially equivalent to the Hyfrecator 2000 in design, operation, intended use, materials, method of preparation, and performance claims. Bench tests were performed comparing the Electricator with the Hyfrecator 2000. Results indicated that the devices are substantially equivalent in their performance.

Hazard analysis evaluations were performed. Results indicated that there are no new hazards presented by the use of the Electricator as compared with the predicate device.

In conclusion, the Delasco Electricator is substantially equivalent to the predicate device in methods of operation, intended use, and results derived from operation.

Submitted By: Deborah Grafelman
President
Delasco
608 13th Ave.
Council Bluffs, IA 51501
(712) 323-1156

Contact Person: Deborah Grafelman
Date: January 2, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2001

Ms. Deborah L. Grafelman
President
Dermatologic Lab & Supply, Inc.
608 13th Avenue
Council Bluffs, Iowa 51501

Re: K010025
Trade Name: Delasco Electricator
Regulatory Class: II
Product Code: GEI
Dated: January 2, 2001
Received: January 3, 2001

Dear Ms. Grafelman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K010025

DEVICE NAME: Delasco Electricator

INDICATIONS FOR USE:

The Delasco Electricator is intended to be utilized for destroying skin lesions and to coagulate small bleeders by applying high frequency current.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010025